

REMARKS

Applicant wishes to thank the Examiner for the attention accorded to the instant application, and respectfully requests reconsideration of the application as amended.

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 37-38, 40-44 and 45-54 are pending in the present application. Claim 1 has been amended to recite a method for therapeutically treating a subject selected from the group consisting of a young mammal at the age of weaning, a young mammal suffering from milk crust, a mammal treated with antibiotics, a mammal having sensitivity to lactose, a mammal suffering from celiac disease, a mammal suffering from food allergy, an aged mammal and a mammal with a short intestine. Claim 1 incorporates subject matter of Claim 38. Claim 38 has been amended to remove the reference to a mammal having a sensitivity to lactose. Claim 38 has been amended to include the combination of polydextrose and an amount of polyol. Support for this amendment can be found in previously filed Claim 39. No new matter has been entered into the disclosure by way of the present amendments.

Applicant respectfully submits new Claims 45-54 for examination. Claim 45 is directed to, *inter alia*, a method for therapeutically treating a mammal with celiac disease and suffering from a disease or disorder caused by accumulation of lactic acid in the colon, said method comprising administering to said subject a food product comprising an amount of polydextrose effective to reduce the lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of said subject. Claim 46 is directed to, *inter alia*, polydextrose being administered in combination with at least one polyol. Claim 47 is directed to, *inter alia*, a method for therapeutically treating a subject suffering from a disease or disorder caused by accumulation of lactic acid in the colon, the disease or disorder selected from the group consisting of acidosis, inflammation and diarrhea, said method comprising administering to said

subject a food product comprising a combination of at least one polyol and an amount of polydextrose effective to reduce the lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of said subject. Claim 48 is directed to, *inter alia*, a method for preventing accumulation of lactic acid in the colon of a subject with a risk for imbalanced colon fermentation, comprising administering to a subject selected from the group consisting of a young mammal at the age of weaning and a young mammal suffering from milk crust an amount of polydextrose effective to reduce lactic acid accumulation in the colon of said subject. Claim 49 is directed to, *inter alia*, the polydextrose being administered in a food composition selected from the group consisting of yogurt, baby's milk formula, sour milk, curdled milk, dry milk and crout. Claim 50 is directed to, *inter alia*, the food composition being a sour food or feed product. Claim 51 is directed to, *inter alia*, the food composition being selected from the group consisting of yogurt, baby's milk formula, sour milk, curdled milk, dry milk and crout. Claim 52 is directed to, *inter alia*, an orally administrable food composition for preventing accumulation of lactic acid in the colon of a subject with a risk for imbalanced colon fermentation, comprising administering to a subject selected from the group consisting of a young mammal at the age of weaning and a young mammal suffering from milk crust an amount of polydextrose effective to reduce lactic acid accumulation in the colon of said subject. Claim 53 is directed to, *inter alia*, the orally administrable food composition being selected from the group consisting of a dry, or semidry or liquid food product, a powder, a spray, a syrup, a sugar substitute, a candy or sweet, a frozen dairy product, a meat product, a health drink, a baby food, crout, a dairy product, the dairy produce including yogurt, baby's milk formula, sour milk, curdled milk and dry milk. Claim 54 is directed to, *inter alia*, the polydextrose being administered in combination with at least one polyol.

No new matter has been added by way of the aforementioned Claim additions. For example, Applicant directs the Examiner's attention to Example 5, page 19 and original Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 37-38, 40-44. Applicant submits that the identified sections are presented only for the Examiner's convenience and is not intended to be an exhaustive list of support.

Treating a mammal with celiac disease, as recited in new Claim 45 has full support in the specification. Claim 45 recites treating a subject suffering from celiac disease, which causes imbalanced colon fermentation and accumulation of lactic acid. Please refer to the attached Wikipedia article for a fuller description of celiac disease. It is well known to those of ordinary skill in the art that celiac disease makes the small intestine perform poorly and as a consequence, carbohydrates are not absorbed in the small intestine as they should be and larger quantities enter the colon. This causes an overload of rapidly fermented carbohydrates in the first part of the colon which results in microorganisms proliferating in large quantities. When the mass of rapidly digested carbohydrates has been consumed and the huge amount of microorganisms is left without a food source, there will be imbalance in the colon fermentation and accumulation of lactic acid. This is further described on page 2-3 of the present application.

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 42 stand rejected under 35 U.S.C. §112 first paragraph as allegedly failing to comply with the written description requirement. Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 42 stand rejected under 35 U.S.C. §112 second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 1, 5-13, 16-20, 24, 27, 28, 30, 32-35 and 37-44 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 5,711,982 ("Takemori") in view of American Family Physician, volume 65, Number 9, May 1, 2002, pages 1845-1850 ("Swagerty"). Claim 26 stands rejected under 35 U.S.C. §103(a) as allegedly

unpatentable over Takemori in view of Swagerty and U.S. Patent 5,601,863 to Borden et al. ("Borden"). Claims 38, 40 and 41 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by J. Lab. Clin. Med., May 1985, pages 585-592 ("Solomons"). Claims 38, 40 and 41 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Am. J. Clin. Nutr 2000, 72: 1503-9 ("Jie"). Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 37-44 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over Claims 38-58 of co-pending Application No. 10/341,748

In view of the following remarks, Applicants request further examination and reconsideration of the present patent application.

Rejections under 35 U.S.C. §112

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 42 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 42 stand rejected under 35 U.S.C. §112 second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 has been amended to remove the term "subject suffering from a disease or disorder caused by accumulation of lactic acid in the colon." It specifically recites the subjects to which the product described in the present application is administered. More specifically, it recites a method for therapeutically treating a subject selected from the group consisting of a young mammal at the age of weaning, a young mammal suffering from milk crust, a mammal treated with antibiotics, a mammal having sensitivity to lactose, a mammal suffering from eeliac disease, a mammal suffering from food allergy, an aged mammal and a mammal with a short intestine. The subjects have full and specific support in the specification, and as such, meets the description requirement under 35 U.S.C. §112, first paragraph. Moreover, the subjects were also

listed previously in Claim 38, and these were incorporated into Claim 1. Further, these subjects are specific and clearly understood by the skilled artisan. It is noted that Claim 38 was not rejected under either the first or second paragraph of 35 U.S.C. §112.

Thus the rejection of Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 42 under 35 U.S.C. §112, first paragraph and second paragraph, is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 42 is earnestly solicited.

Rejections under 35 U.S.C. §103

Claims 1, 5-13, 16-20, 24, 27, 28, 30, 32-35 and 37-44 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Takemori in view of Swagerty.

The subject matter of Claim 1 et seq. is directed to, inter alia, a method for therapeutically treating a subject selected from the group consisting of a young mammal at the age of weaning, a young mammal suffering from milk crust, a mammal treated with antibiotics, a mammal suffering from food allergy, an aged mammal and a mammal with a short intestine, said method comprising administering to said subject a food product comprising a combination of at least one polyol and an amount of polydextrose effective to reduce lactic acid accumulation in the colon by sustaining and controlling fermentation throughout the colon of said subject.

Takemori teaches a low-calorie and sugar-less foodstuff which holds taste and feel of conventional foodstuffs thereby promoting health. See Column 2 lines 1-5 of Takemori. Takemori also teaches a method to obtain de-lactose milk by conjugating the fat with the protein in the milk product. See Column 3 lines 3-11 of Takemori.

Swagerty teaches that people who are unable to digest sufficient amounts of lactose experience pain and bloating, excessive flatus and watery stool following the ingestion of foods containing lactose. See Abstract of Swagerty. Swagerty also teaches that avoidance of these

symptoms can occur if a patient reduces their overall lactose intake, and drink lactose-reduced milk. See left column page 1849 of Swagerty.

As correctly stated on page 8 of the Official Action, Takemori does not teach administration to subjects having particular diseases or disorders. Further, Takemori does not teach or suggest any method of treatment. Swagerty also does not teach or suggest any method of treatment; Swagerty simply teaches avoidance of symptoms by monitoring lactose intake. Inasmuch as neither Takemori nor Swagerty teach, disclose or suggest any methods of treatment, the combination cannot suggest the present method of treatment -- let alone the subjects being treated or the use of polydextrose and polyol. The claimed invention would not have been rendered obvious to one of ordinary skill in the art by the combination of the teachings in Takemori and Swagerty. Neither the Takemori reference nor the Swagerty reference teach or suggest a method of treatment as recited in Claim 1 and all claims depending therefrom of the present application.

Claim 38 is directed to, inter alia, a method for preventing accumulation of lactic acid in the colon of a subject with a risk for imbalanced colon fermentation, comprising administering to a subject selected from the group consisting of a mammal treated with antibiotics, a mammal suffering from celiac disease, a mammal suffering from food allergy, an aged mammal and a mammal with a short intestine an amount of polydextrose in combination with an amount of at least one polyol effective to reduce lactic acid accumulation in the colon of said subject.

The combination of Takemori and Swagerty also does not teach or suggest the subject matter of Claim 38 et seq. Takemori and Swagerty, in combination, suggest at most, a method to remove lactose from milk and a regimen in where people who cannot digest lactose should drink lactose reduced milk. Applicants reiterate the comments hereinabove with respect to Takemori and Swagerty, the contents of which are incorporated by reference. As described above, neither

Takemori nor Swagerty teach or suggest any method of treatment. Therefore, the combination of Takemori and Swagerty do not teach or suggest a method for preventing accumulation of lactic acid in the colon of a subject with a risk for imbalanced colon fermentation, comprising administering to a subject selected from the group consisting of a young mammal at the age of weaning, a young mammal suffering from milk crust, a mammal treated with antibiotics, a mammal suffering from celiac disease, a mammal suffering from food allergy, an aged mammal and a mammal with a short intestine, or the use of polydextrose or polyol, as recited in Claim 38 and all claims depending therefrom of the present application.

Thus the rejection of Claims 1, 5-13, 16-20, 24, 27, 28, 30, 32-35 and 37-44 over Takemori in view of Swagerty is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-20, 24, 27, 28, 30, 32-35 and 37-44 is earnestly solicited.

Claim 26 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Takemori in view of Swagerty and U.S. Patent 5,601,863 to Borden et al. (Borden).

The discussion of the combination of Takemori and Swagerty have been discussed above, the contents of which is incorporated by reference. Borden does not cure these deficiencies.

Borden teaches polymerization of polydextrose by exposing the polydextrose to hydrogen gas in the presence of a hydrogenation catalyst or a hydride donor. See column 1 line 59 to column 2 line 2. Borden does not teach or suggest a method of treatment for any subject. Further, Borden does not teach a method to reduce lactic acid accumulation in the colon, as recited in Claim 1, from which Claim 26 depends.

Inasmuch as Takemori and Swagerty do not teach or suggest a method of treatment of any subject and Borden does not teach or suggest a method of treatment, therefore the combination of Takemori, Swagerty and Borden does not render the claimed invention obvious because the combination lacks at least a teaching or suggestion a method of treatment for any

subject. Thus the rejection of Claim 26 over Takemori in view of Swagerty and Borden is overcome. Withdrawal of the rejection and allowance of Claim 26 is earnestly solicited.

Claims 38, 40 and 41 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Solomons.

Claim 38, from which Claim 40 and 41 depend, recites a combination of polydextrose and a polyol. The Official Action states on page 3 that does not teach administration of a polyol in combination with polydextrose. Thus, the subject matter of Claims 38, 40 and 41 is not taught by Solomons a position of which the USPTO concurs.

Therefore the rejection of Claims 38, 40 and 41 in view of Solomons is overcome. Withdrawal of the rejection and allowance of Claims 28, 40 and 41 is earnestly solicited.

Claims 38, 40 and 41 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Jie.

Claim 38, from which Claim 40 and 41 depend, recites a combination of polydextrose and a polyol. As the Official Action states on page 2, Jie does not teach administration of a polyol in combination with polydextrose. Inasmuch as there is no discussion of polyol in this regard, thus, Jie cannot teach, disclose or suggest the use of the combination of polyol and polydextrose.

Therefore this rejection of Claims 38, 40 and 41 in view of Jie is overcome. Withdrawal of the rejection and allowance of Claims 38, 40 and 41 is earnestly solicited.

Claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35 and 37-44 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over Claims 38-58 of co-pending Application No. 10/341,748.

A terminal disclaimer for any patent term extending beyond the term of co-pending Application No. 10/341,748 was filed with the USPTO on 10/4/07 and was accepted by the

USPTO on 10/19/07. Therefore this rejection is believed to be moot. Withdrawal of the rejection and allowance of Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-36 is requested.

Applicant believes that the paper submitted herein provides a complete response to the Office Action, and the present case is in condition for allowance. Therefore, in view of the foregoing, Applicant respectfully requests reconsideration, withdrawal of all rejections, and allowance of all pending claims in due course. If the Examiner believes that a telephone conference with the Applicants attorneys would be advantageous to the disposition of this case, the Examiner is requested to contact the undersigned, Applicant's attorney, at the number provided below.

Respectfully submitted,

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